

REMARKS

Reconsideration is respectfully requested. Claims 1- 19 and 33-37 are pending. Claim 1, 16, 17 and 19 have been amended. Claims 20-32 have been canceled. New claims 33 –37 have been added.

Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections made by the Patent Office. Applicants reserve the right to pursue prosecution of any presently excluded claim embodiments in future continuation and/or divisional applications.

CLAIM AMENDMENTS

Claim 1 has been amended. The support is found in page 6, lines 4-5, and page 44, lines 22-25, page 46, lines 4-5 and lines 21-23, and page 47, lines 24-25.

Claims 33 – 37 have been added. The support for claim 33 is found in page 18, line 29, page 19, line 13, and page 20, line 3. The support for claim 34 is found in page 10, line 10. The support for claim 35 is found in page 19, line 20. The support for claim 36 is found in page 18, lines 15-16. The support for claim 37 is found in page 20, lines 24-25.

SPECIFICATION

The Examiner objects to the terms "herein" and "thereto" in the Abstract.

The specification has been amended to remove those terms. Applicants request the withdrawal of the objections.

CLAIMS OBJECTIONS

The Examiner objects to the claims on the basis of not in accordance with 37 CFR 1.126 because there are two claims numbered "15".

Misnumbered claims 15-18 have been renumbered 16-19. Applicants request the withdrawal of the objection.

REJECTION OF CLAIM 17 UNDER 35 U.S.C. § 112

Claim 17 stands rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, claim 17, which has been renumbered from incorrectly numbered 16, has been previously amended to depend on claim 16, and such amendment is not reflected in the status identifier.

The status identifier has been corrected to reflect the status of the claim. Applicants request the withdrawal of the objection

REJECTIONS OF CLAIMS 1-4, 8, 14 AND 17-19 UNDER 35 U.S.C. § 103

Claims 1-4, 8, 14, and 17-19 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Gao et al. (Biotechnic & Histochemistry, 1995, vol. 70, no 4, pages 211-216) ("*Gao*") in view of Stimpson et al (US 5,599,668) ("*Stimpson*").

When rejecting claims under 35 U.S.C. §103, the Examiner bears the burden of establishing a *prima facie* case of obviousness. See, e.g., *In re Bell* 26 USPQ2d 1529 (Fed. Cir. 1993); M.P.E.P. Section 2142. To establish a *prima facie* case, the prior art reference(s) must teach or suggest each and every limitation of the rejected claims. *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991); M.P.E.P. §2142.

***Gao* and *Stimpson*, alone or in combination, do not teach or suggest each and every limitations of claims 1-4, 8, 14, and 17-19.**

Claims 2-4, 8, 14, and 17-19 depends on claim 1, which requires "counting individual analyte particles after said processing step using digital information to detect the presence of said particles."

The Examiner concedes that *Gao* failed to teach the step of counting objects after said processing step using digital information in determining at least whether the substance of interest is present in the sample. Thus, *Gao* does not teach "counting individual analyte particles" as claim 1 required. This failure is not compensated by *Stimpson*.

Stimpson teaches a waveguide binding assay method involves detecting the scattering of light directed into the waveguide. See Abstract. The scattered light may be detected visually or by photoelectric means, such as CCD camera. See col. 21, line 49 to col. 22, line 4. *Stimpson* also teaches that the digital information obtained may be displayed on a monitor, or stored in RAM or any other storage device for further manipulation. In addition, image processing software may be used to analyze the digital information and determine boundaries or contours of each situs. The assay can be quantitative. See col. 22, lines 20-22, 34-37 and 51. However, the quantitative measure as taught by *Stimpson* is different from "counting individual analyte particles." *Stimpson* teaches quantitation by comparing light scattering at first time with the scattering at second time, thus obtaining kinetic information by measuring the time-dependency of the increase or decrease of light scattering. *Stimpson* further teaches that such kinetic information is correlated to a quantitative measure of analyte concentration in the sample solution. See col. 22, lines 48 – 62. Therefore, *Stimpson* only teaches quantitative measuring of the concentration of

analyte. It does not teach "counting individual analyte particles" as claim 1 requires. The individual analyte particles were never counted. As such, *Stimpson* does not meet this claim limitation.

Thus, the cited references, in combination, fail to teach each and every limitation of claims 1-4, 8, 14, and 17-19, either expressly or inherently. Because the combined references fail to teach every claimed limitation, claims 1-4, 8, 14, and 17-19 are not obvious over *Gao* in view of *Stimpson*. Applicants request the withdrawal of the objection.

REJECTIONS OF CLAIMS 5, 9 – 13, AND 15 UNDER 35 U.S.C. § 103

Claims 5, 9-13, and 15 stand rejected under 35 U.S.C. §103(a) as being unpatentable over *Gao* in view of *Stimpson*, and further in view of *De Brabander* (The Amer. J. Anat., 1989, vol. 185, pages 282-295) ("*De Brabander*").

Claims 5, 9-13, and 15 depend on claim 1, which requires "counting individual analyte particles after said processing step using digital information to detect the presence of said particles."

As discussed above, neither *Gao* nor *Stimpson* teaches "counting individual analyte particles." Similarly, *De Brabander* fails to compensate for the failure of the *Gao* and *Stimpson* references.

De Brabander teaches a microscopic technique aimed at visualizing colloidal gold particle as dynamic markers at the light microscope level, based on the use of contrast enhancement by video techniques and digital image processing. See page 282, Abstract. However, it does not teach "counting individual analyte particles." The individual analyte particles were never counted.

Because the combined references fail to teach every claimed limitation, claims 5, 9-13, and 15 are not obvious over *Gao* in view of *Stimpson*, and further in view of *De Brabander*. Applicants request the withdrawal of the objection.

REJECTIONS OF CLAIMS 6, 7 AND 16 UNDER 35 U.S.C. § 103

Claims 6, 7 and 16 stand rejected under 35 U.S.C. §103(a) as being unpatentable over *Gao* in view of *Stimpson*, and further in view of *Oberhardt* (US 6,251,615) ("*Obderhardt*").

Claims 6,7 and 16 depend on claim 1, which requires "counting individual analyte particles after said processing step using digital information to detect the presence of said particles."

As discussed above, neither *Gao* nor *Stimpson* teaches "counting individual analyte particles." Similarly, *Obderhardt* fails to compensate for the failure of the *Gao* and *Stimpson* references.

Obderhardt teaches a method of analyzing cells in a carrier solution by means of affinity interactions between specific surface molecules of the cells and test surface. See col. 2, lines 24-29.

USSN: 10/084,632
Filing Date: February 25, 2002

However, it does not teach "counting individual analyte particles." Individual analyte particles were never counted. As such, *Obderhard* does not meet this claim limitation either.

Because the combined references fail to teach every claimed limitation, claims 6, 7 and 16 are not obvious over *Gao* in view of *Stimpson*, and further in view of *Obderhard*. Applicants request the withdrawal of the objection

CONCLUSION

Applicants respectfully submit that all pending Claims of the captioned Application satisfy all requirements for patentability and are in condition for allowance. An early indication of the same is therefore respectfully requested.

If the Examiner determines that prosecution of the instant application would benefit from a telephone interview, the Examiner is invited to call the undersigned attorney at (415) 781-1989.

Respectfully submitted,

DORSEY & WHITNEY LLP

Dated: 2/6/06

By: Robin M. Silva

555 California Street
Suite 1000
San Francisco, CA 94104-1513
Telephone: (415) 781-1989
Fax No. (415) 398-3249

Robin M. Silva, Reg. No. 38,304
Filed under 37 C.F.R. § 1.34

Customer No. 32940